SEP - 7 2005

K051966

Section D

510(k) Summary
[As required by 21 CFR 807.92]

I. Submitter:

A. Name: Worldwide Medical LLC

B. Address: 13 Spectrum Pointe Drive, Lake Forest, California 92630

C. Phone and Fax Numbers: Phone: (949) 598-8378 X208
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D. Contact Person: Kevin J. Gadawski

II. Date of Preparation of this Summary: July15, 2005

III. Trade Name: First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Ampethamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP).

IV. Common Name: Home use drug of abuse rapid screening test for Marijuana (THC), Cocaine (COC), Ampethamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) in urine.

V. Classification Name: Immunoassay for the qualitative detection of drugs of abuse in urine.

VI. The Marketed Products to Which Equivalence is Claimed: The First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP), that is the subject of this submission is identical to the Ameditech ImmuTest Drug Screen Cup in terms of product design, performance characteristics, materials of construction and manufacturing process. It is also substantially equivalent to the Accu-Stat Home Drug Test Cup, and other commercially available drug screening tests, that qualitatively measure the presence of target drugs or metabolites by visual color one-step immunoassay technology.

VII. Statement of Intended Use Compared to Other Products: The intended use of the First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) is substantially equivalent to the listed products; it

is a preliminary, rapid screening test for the detection of between one and seven of the above listed drugs and their metabolites in urine (depending on configuration). This product is intended to be the first step in a two step process to provide consumers, including but not limited to concerned parents, with information regarding the presence of Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) and their metabolites in a urine sample. Information regarding the second step, confirmatory testing, is provided. The First Check Multi Drug Cup 7 utilizes the following cut-off concentrations: Marijuana at 50 ng/ml, Cocaine at 300 ng/ml, Amphetamine at 1000 ng/ml, Methamphetamine at 1000 ng/ml, Ecstasy at 500 ng/ml, Opiates at 2000 ng/ml, and Phencyclidine at 25 ng/ml. The predicate device (Ameditech ImmuTest Drug Screen Cup) is intended for professional use while the First Check® Multi Drug Cup 7 is intended for OTC use.

VIII. Discussion of Technological Characteristics: The First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP), like other commercially available drug screening tests, qualitatively detects the presence or absence of the above listed drugs and their metabolites in urine, using a one step, rapid chromatographic immunoassay which operates under the principle of recognition and formation of specific antibody/target drug complexes.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly. If a control line does not appear for any reason, the results are considered invalid and should not be interpreted. The sample should either be retested using a new First Check Multi Drug Cup 7 or the sample should be mailed in for confirmation.

Examples of predicate devices include the First Check® Home Drug Tests using a single or multi-drug display and the Accu-Stat Drugs of Abuse Home Test Cup. The analytical studies of the identical Ameditech, Inc ImmuTest Drug Screen Cup (K040092 and K042975) indicate that the drug test reacts specifically with the above listed drugs and their metabolites. A consumer study using the First Check® Home Drug Test for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) demonstrates that the test exhibits excellent overall performance in the hands of lay users. The data supports the conclusion that the consumer can use the First Check® Home Drug Test for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) to obtain immediate,

preliminary information regarding the possible use of THC, COC, AMP, MET, MDMA, OPI and PCP.

IX. Safety and Effectiveness: Because the First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) is identical to the Ameditech ImmuTest Drug Screen Cup Test that is legally marketed for professional use under K040092 and K042975, and because no special skills, training, education, or licensure are required to collect a urine sample and activate the test, there is no issue regarding the safety or effectiveness of the product to perform its intended function, i.e., to screen urine for the presence or absence of THC, COC, AMP, MET, MDMA, OPI or PCP and their metabolite(s).

Because the labeling of the First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) is substantially equivalent to a variety of rapid screening tests currently in commercial distribution, including the First Check Home Drug Test Kit, the Phamatech At Home™ Drug Test Cup and the Accu-Stat Home Drug Test Cup, and there have been no reports of consumer inability to follow instructions or interpret results over the many years in which these products have been purchased by the general public, and due to the successful responses from the consumer study for the First Check® Multi Drug Cup 7, it should be concluded that the product can be used effectively by the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Kevin J. Gadawski
President
Worldwide Medical, LLC
13 Spectrum Pointe Drive
Lake Forest, California 92630

SEP - 7 2005

Re: k051966
Trade/Device Name: First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP)
Regulation Number: 21 CFR § 862.3100
Regulation Name: Enzyme Immunoassay, Amphetamine
Regulatory Class: II
Product Code: DKZ, LDJ, DIO, LAF, DJG and LCM
Dated: July 15, 2005
Received: July 20, 2005

Dear Mr. Gadawski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section A

510(k) Number (if known): K051966

Device Name: First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP)

Indications for Use:

The First Check® Multi Drug Cup 7 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI) and Phencyclidine (PCP) is a screening test for the rapid detection of one to seven of the above listed drugs in a variety of combinations in human urine. The designated cut-off concentrations of these drugs are as follows: Marijuana at 50 ng/ml, Cocaine at 300 ng/ml, Amphetamine at 1000 ng/ml, Methamphetamine at 1000 ng/ml, Ecstasy at 500 ng/ml, Opiates at 2000 ng/ml, and Phencyclidine at 25 ng/ml.

Special condition for use statement:

This device provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided.

Prescription Use_____ AND/OR Over-The-Counter Use__X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED.)

Division Sign-Off Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device Evaluation and Safety

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